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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,926	- 11/14/2003	· Lyn Hughes	A01290C	4816
21898 ROHM AND 1	7590 01/11/2008 HAAS COMPANY	EXAMINER		
PATENT DEPARTMENT			AZPURU, CARLOS A	
100 INDEPENDENCE MALL WEST PHILADELPHIA, PA 19106-2399			ART UNIT	PAPER NUMBER
	,		1615	•
			MAIL DATE	DELIVERY MODE
•			01/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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•		Application No.	Applicant(s)				
		.10/713,926	HUGHES ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Carlos A. Azpuru	1615				
Period for	- The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
	ORTENED STATUTORY PERIOD FOR REPLY	/ IS SET TO EXPIRE 1 MONTH(	S) OR THIRTY (30) DAYS				
WHICI - Extens after S - If NO   - Failure Any re	HEVER IS LONGER, FROM THE MAILING DAS sions of time may be available under the provisions of 3 CFR 1.13 IX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, ply received by the Office later than three months after the mailing dipatent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION B6(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status							
1)🛛 🗎	Responsive to communication(s) filed on 20 Au	igust 2007.	·				
•	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.						
3) 🗌 🥴							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Dispositio	on of Claims						
4)⊠ Claim(s) <u>1-10</u> is/are pending in the application.							
•	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
	6) Claim(s) is/are rejected.						
	Claim(s) is/are objected to.						
8)🖾 🤇	Claim(s) <u>1-10</u> are subject to restriction and/or e	election requirement.					
Application	on Papers						
	he specification is objected to by the Examine	•					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
•	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
I	Replacement drawing sheet(s) including the correcti	ion is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).				
11)∐ T	he oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority u	nder 35 U.S.C. § 119						
12) 🗌 A	acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:							
•	1. Certified copies of the priority documents have been received.						
2	2. Certified copies of the priority documents have been received in Application No						
;	3. Copies of the certified copies of the priority documents have been received in this National Stage						
	application from the International Bureau	' ' '					
* Se	ee the attached detailed Office action for a list of	of the certified copies not receive	d.				
Attachment(	s)	•					
	of References Cited (PTO-892)	4) Interview Summary					
· =	of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5)  Notice of Informal P					
	No(s)/Mail Date	6) Other:					

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## Election/Restrictions

A review of the prior restriction requirement and the response finds that the restriction requirement was improperly executed since the examiner in question is not an expert in this area. The following restriction takes its place. This examiner would like to apologize for the added, but necessary requirement.

This application contains claims directed to the following patentably distinct species: 1) The extended release oral dosage coated formulation of claim 2. 2) The enteric coated polymer formulation with an added matrix polymer of claim 3. The species are independent or distinct because extended release has a distinct delivery profile from that of enteric polymer formulations which do not begin to deliver bioactive until they reach the intestinal tract as triggered by a change in pH levels.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4-10 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Additionally if either Group 1) or Group 2) above are elected the following election must be made:

This application contains claims directed to the following patentably distinct species: a) Additional coating polymers of claim 5 or claim 9 (pick one), b) plasticizers of claim 7, c) filler of claim 7. The species are independent or distinct because each polymer, plasticizer and filler has distinct properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4, and 10 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

So to summarize, applicant is requested to elect between the etxnded release and the enteric coating formulations. In addition to this election, applicant is then asked to elect which polymer may be further added, as well as which plasticzer and filler are possible added to either elected formulation of the first election between Group 1) and 2).

A telephone call was made to James G Vouros on 01/06/2008 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000

Ćarlos A. Azpuru∖ Primary Examiner Art Unit 1615 │

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